

Notice of Allowability

Application No.

09/880,881

Applicant(s)

MAYER ET AL.

Examiner

Shengjun Wang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to October 3, 2005.
2. ☒ The allowed claim(s) is/are 3-16 and 20.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

SHENGJUN WANG
PRIMARY EXAMINER

DETAILED ACTION

The supplemental declaration filed October 3, 2005 has been entered and considered. The supplemental declaration is sufficient to overcome the rejections under 35 U.S.C 251 set forth in the prior office action.

Examiner's Amendment

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Amend the application as follow:

In the claims;

Amend the claims as attached.

Note the examiner's amendments do not affect the scope of the claimed invention, but put the claims in a proper form, i.e., underline any new claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER
Shengjun Wang
Primary Examiner
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1. (Canceled)

2. (Canceled)

3. (Pending) A formulated pharmaceutical composition comprising an addictive substance and at least one nontoxic synthetic substance that provides an improved effect for the addictive substance if used alone and that blocks the N-methyl-D-aspartate receptor and consists essentially of a morphinan or blocks a major intracellular consequence of N-methyl-D-aspartate receptor activation, the addictive substance being selected from the group consisting of alfentanil, alphaprodine, anileridine, bezitramide, codeine, dihydrocodeine, diphenoxylate, ethylmorphine, fentanyl, heroin, hydrocodone, hydromorphone, isomethadone, levomethorphan, levorphanol, metazocine, methadone, metopon, morphine, opium extracts, opium fluid extracts, powdered opium, granulated opium, raw opium, tincture of opium, oxycodone, oxymorphone, pethidine, phenazocine, piminodine, racemethorphan, racemorphan and pharmaceutically acceptable salts thereof.

4. (Pending) A formulated pharmaceutical composition comprising an addictive substance and a non-toxic synthetic substance, the addictive substance being selected from the group consisting of alfentanil, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, isomethadone, levorphanol, methadone, morphine, oxycodone, oxymorphone, pethidine, and pharmaceutically acceptable salts thereof, the non-toxic synthetic substance providing an improved effect for the addictive substance if used alone and being selected from the group consisting of dextromethorphan, dextrorphan, and pharmaceutically acceptable salts thereof.

5. (Pending) A formulated pharmaceutical composition comprising an addictive substance and a non-toxic synthetic substance, the addictive substance being selected from the group consisting of alfentanil, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, isomethadone, levorphanol, morphine, oxycodone, oxymorphone, pethidine, and pharmaceutically acceptable salts thereof, the non-toxic synthetic substance being a blocker of the N-methyl-D-aspartate receptor and consisting essentially of morphinans, and providing an improved effect for the addictive substance if used alone.
6. ((Pending)) A composition according to claims 3, 4 or 5 wherein the addictive substance is selected from the group consisting of alfentanil, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, isomethadone, methadone, morphine, oxycodone, oxymorphone, pethidine, and pharmaceutically acceptable salts thereof.
7. (Pending) A composition according to claims 3, 4 or 5 wherein the addictive substance is selected from the group consisting of alfentanil, codeine, dihydrocodeine, fentanyl, isomethadone, methadone, pethidine, and pharmaceutically acceptable salts thereof.
8. (Pending) A composition according to claims 3, 4 or 5 wherein the addictive substance is selected from the group consisting of codeine, methadone, and pharmaceutically acceptable salts thereof.
9. (Pending) A composition according to claims 3, 4 or 5 wherein the addictive substance includes morphine or a pharmaceutically acceptable salt thereof.
10. (Pending) A composition according to claims 3, 4 or 5 wherein the addictive substance includes oxycodone or a pharmaceutically acceptable salt thereof.

11. (Pending) A composition according to claims 3, 4 or 5 wherein the addictive substance includes hydrocodone or a pharmaceutically acceptable salt thereof.
12. (Pending) A composition according to claims 3, 4 or 5 wherein the addictive substance includes oxymorphone or a pharmaceutically acceptable salt thereof.
13. (Pending) A composition according to claim 3, 4 or 5 wherein the addictive substance includes hydromorphone or a pharmaceutically acceptable salt thereof.
14. (Pending) A composition according to claims 3, 4 or 5, in oral dosage form.
15. (Pending) A composition according to claims 3, 4 or 5, in sustained release dosage form.
16. (Pending) A composition according to claims 3, 4 or 5, in oral dosage and sustained release dosage form.
17. (Canceled)
18. (Canceled)
19. (Canceled)
20. (New) A formulated pharmaceutical composition comprising an addictive substance and at least one nontoxic synthetic substance that blocks the N-methyl-D-aspartate receptor or a major intracellular consequence of N-methyl-D-aspartate receptor activation, selected from pyrroloquinoline quinone and cis-4-(phosphonomethyl)-2-piperidinecarboxylic acid., the addictive substance being selected from the group consisting of alfentanyl, alphaprodine, anileridine, bezitramide, codeine, dihydrocodeine, diphenoxylate, ethylmorphine, fentanyl, heroin, hydrocodone, hydromorphone, isomethadone, levomethorphan, levorphanol,

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metazocine, methadone, metopon, morphine, opium extracts, opium fluid extracts, powdered
opium, granulated opium, raw opium, tincture of opium, oxycodone, oxymorphone, pethidine,
phenazocine, piminodine, racemethorphan, racemorphan and pharmaceutically acceptable salts
thereof.